EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

KRIS BLOOM, by and through her natural mother and guardian, Astrid Moise, and Astrid Moise, individually, Plaintiffs, v. MEAD JOHNSON & COMPANY, LLC, a/k/a MEAD JOHNSON NUTRITION COMPANY, Defendant.	Case No.: Judge: **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiffs, Kris Bloom and Astrid Moise, (collectively, "Plaintiffs"), bring this action against Defendant Mead Johnson & Company, LLC, a/k/a Mead Johnson Nutrition Company ("Defendant" or "Mead"), asserting claims arising from the catastrophic injury they sustained as a direct result of Defendant's design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of bovine-based formulas and/or fortifiers ("bovine formula") to premature infants.

INTRODUCTION

1. Defendant knowingly advertised, promoted, supplied, manufactured, provided instructions, marketed, labeled, packaged, sold, and placed in the stream of commerce its baby formula, Enfamil, which is unsafe and unreasonably dangerous for its intended use and purpose.

2. Enfamil causes a significant increase in incidences of necrotizing enterocolitis when administered enterally to premature infants.

3. Despite well-known, reliable scientific studies and data establishing the increased risk of necrotizing enterocolitis when Enfamil is administered to premature infants, Defendant knowingly withheld this information from the consuming public, including Plaintiffs.

4. In its quest to maximize profits, Defendant placed its own economic interests over its customers' lives and safety, by deceptively marketing, promoting, and advertising Enfamil as being a safe, alternative to human milk-based formulas and fortifiers, when it knew or should have known that Enfamil was unsafe and unreasonably dangerous for administration to premature infants—including Kris Bloom, due to the increased risk of necrotizing enterocolitis and associated medical conditions that Enfamil causes in premature infants.

5. As a direct and proximate result of Defendant's conduct, as described herein, Kris Bloom was diagnosed with necrotizing enterocolitis, sustaining severe injuries as a cause thereof.

PARTIES

Plaintiffs

6. Astrid Moise is a resident of Hollywood, Broward County, Florida. She is the mother of Kris Bloom, who is a minor.

7. Kris Bloom was born on October 15, 2019, at Jackson Memorial Hospital in Miami, Florida, at 24 weeks gestation and weighing one pound and three ounces.

8. Given her premature birthweight, Kris Bloom was transferred to the Neonatal Intensive Care Unit ("NICU") for care.

9. While in the NICU, Kris Bloom was provided nutrients through an enteral feeding tube. For that process, Kris Bloom was specifically given Enfamil ("formula" and/or "product"), a formula and/or fortifier which is a formula which is bovine based, and which does not contain human milk.

10. Shortly after receiving the formula enterally, Kris Bloom began to suffer from gastrointestinal issues and was diagnosed with NEC.

11. Kris Bloom continues to suffer from severe injury as a result of her NEC caused by Defendant's Enfamil product.

Defendant

12. Mead Johnson Nutrition Company is a Delaware corporation, with its principal place of business in the State of Illinois. Mead Johnson & Company LLC is a Delaware limited liability company. Its citizenship is the State of Illinois, the state of citizenship of its sole member, Mead Johnson Nutrition Company. Unless otherwise indicated, Mead Johnson Nutrition Company and Mead Johnson & Company LLC are collectively referred to herein as "Mead."

13. At all times relevant to this action, Mead conducted, and continues to conduct, a substantial amount of business activity and has engaged in tortious conduct, in whole or in part, in this District. Mead is headquartered in Chicago, Illinois and engaged in interstate commerce in all fifty states when it advertised, promoted, supplied, manufactured, provided instructions, marketed, labeled, packaged, sold, and placed in the stream of commerce Enfamil, an infant formula and/or fortifier, to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public, deriving substantial revenue in this District.

JURISDICTION AND VENUE

14. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because Defendant is a citizen of a state other than the state in which Plaintiffs are citizens.

15. Venue in this District is proper under 28 U.S.C. § 1391, because a substantial part of the events or omissions giving rise to the claims alleged herein occurred in this District.

16. This Court has personal jurisdiction over Defendant because Defendant is headquartered in Chicago, Illinois.

FACTUAL ALLEGATIONS

A. Necrotizing Enterocolitis

17. Necrotizing Enterocolitis ("NEC") is a severe gastrointestinal disease in premature (preterm) infants ("infants").

18. The Centers for Disease Control and Prevention ("CDC") defines preterm birth as when a baby is born before the 37 weeks of full-term pregnancy have been completed.[1] In 2020 alone, preterm birth affected one out of every ten infants born in the United States.[2]

19. NEC is the most common, and frequently dangerous, gastrointestinal emergency in premature infants in the NICU. It is also the most common cause of gastrointestinal-related death among the smallest, most premature infants in the NICU.[3]

20. NEC occurs when tissue in the large intestine, also known as the colon, becomes inflamed.[4] This inflammation damages and kills tissue in the infant's colon.

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[1] Center for Disease Control and Prevention, *Preterm Birth,* https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pretermbirth.htm (last modified Nov. 1, 2021).

[2] *Id.* For context, in 2020, 3,605,201 babies were born in the United States, meaning that more than 360,000 of those babies were born prematurely—*close to 1,000 every day*. https://www.cdc.gov/nchs/data/vsrr/vsrr012-508.pdf

[3] Sheila M. Gephart, RN, BSN, *et al.*, *Necrotizing Enterocolitis Risk: State of Science*, 12 Advances in Neonatal Care 77-89 (2012).

[4] Stanford Children's Health, *Necrotizing Enterocolitis in the Newborn*, https://www.stanfordchildrens.org/en/topic/default?id=necrotizing-enterocolitis-90-P02388 (last visited Feb. 22, 2022).

21. Signs and symptoms of NEC often include abdominal distension, hemorrhage and necrosis of tissue within the intestine, peritonitis,[5] intestinal perforation, discomfort, and death.[6]

22. The NEC diagnosis is commonly determined with the use of Modified Bell's Staging Criteria, ranging from Stage IA (suspected NEC) to the most severe at Stage IIIB (advanced, severely ill, perforated bowel).[7] The Modified Bell's Staging Criteria incorporate systemic, intestinal, and radiological signs to adequately diagnose, stage, and treat NEC.

23. In some infants, NEC is mild. In others, however, symptoms are severe and life-threatening. Mild cases of NEC may be effectively treated by withholding enteral feeds,[8] decompressing the stomach with a nasogastric tube, and/or starting broad-spectrum antibiotics.[9]

24. In advanced cases, however, NEC may lead to surgery, extensive intestinal necrosis, and death.[10] The mortality rate for NEC patients ranges from 10% to 50% and approaches 100% for patients with the most severe form of the disease.[11]

25. If the infant survives the disease, the long-term outcomes present a multitude of health issues. Surgical NEC survivors are much more likely to have feeding difficulties and gastrointestinal ostomies from ages six months to 36 months than those without an NEC

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[5] Peritonitis is defined as redness, swelling, and inflammation of the tissue that lines the abdomen.

[6] Anand RJ, *et al.*, *The Role of the Intestinal Barrier in the Pathogenesis of Necrotizing Enterocolitis,* 27 Shock 124–33 (2007).

[7] Josef Neu, MD, *Necrotizing Enterocolitis, The Search for a Unifying Pathogenic Theory Leading to Prevention*, 43 Pediatr. Clin. North. Am. 409–432 (1996), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7127724/.

[8] Enteral feeding refers to intake of food through the gastrointestinal (GI) tract. The GI tract is composed of the mouth, esophagus, stomach, and intestines. Enteral feeding may mean nutrition taken through the mouth or through a tube that goes directly to the stomach or small intestine.

[9] PK, Rasiah SV, Ewer AK, *Necrotizing Enterocolitis: Current Perspectives*, 4 Res. Rep. Neonatal 31-42 (2014).

[10] *Id.*

[11] Holman RC, *et al*., *Necrotizing Enterocolitis Hospitalizations Among Neonates in the United States*, 20 Paediatr Perinat Epidemiol, 498–506 (2006).

diagnosis.[12] NEC infants treated with non-surgical intervention are more likely to have a higher risk of failure to thrive, feeding difficulties, neurodevelopmental delay, and open gastrointestinal ostomies when they are between six and twelve months of age.[13]

B. Bovine Formula Increases NEC Risk

26. Bovine milk is used to supplement infant formula. It contains oligosaccharides, some of which are structurally identical, or similar to, those found in human milk.[14]

27. Bovine formula and/or fortifiers are non-prescription. Thus, it does not require a physician's recommendation and is sold with packaging and labels designed to inform the average consumer.

28. The Food and Drug Administration ("FDA") has issued guidance specifically for the labeling of infant formulas, stating, in pertinent part:

> Infant formulas are intended for a vulnerable population and may serve as a sole or primary source of nutrition for some infants during a critical period of growth and development. Caregivers of babies fed infant formula products must be able to trust that the information on the label is truthful, not misleading, and scientifically supported.

29. Bovine formula and/or fortifiers are often given to infants enterally and NEC only occurs after infants have been enterally fed.[15] Several challenges exist for preterm nutritional support. Many preterm infants, especially those born <1500 g and/or <34 weeks gestation, are not

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[12] Ganapathy V. Hay, *et al.*, *Long-term Healthcare Costs of Infants Who Survived Neonatal Necrotizing Enterocolitis*: *A Retrospective Longitudinal Study Among Infants Enrolled in Texas Medicaid*, 13 BMC Pediatrics 127 (2013).

[13] *Id.*; Rees CM, *et al.*, *Neurodevelopmental Outcomes of Neonates with Medically and Surgically Treated Necrotizing Enterocolitis*, 92 Arch. Dis. Child Fetal Neonatal Ed. 193–8 (2007).

[14] Fernando Meli, *et al.*, *Growth and safety evaluation of infant formulae containing oligosaccharides derived from bovine milk: a randomized, double-blind, noninferiority trial*, 14 BMC PEDIATRICS 306 (2014).

[15] Siggers RH, *et al.*, *Nutritional Modulation of the Gut Microbiota and Immune System in Preterm Neonates Susceptible to Necrotizing Enterocolitis*, 22 J Nutr. Biochem 511-21 (2011).

able to breastfeed.[16] The suck-swallow-breathe rhythm of oral feeding may not be possible for preterm infants because of coordination issues and/or low body stores of energy.[17]

30. Several studies establish that bovine formulas and/or fortifiers lead to a higher incidence of NEC in preterm infants than human milk does.[18] An exclusively human milk-based diet is associated with a lower rate of NEC than a diet of human milk and bovine-based products.

31. In 1990, a landmark study was published linking bovine formula to NEC.[19] The authors conducted two parallel dietary studies, involving 926 very low birth weight infants. In Study A, infants were randomly assigned to pasteurized banked donated breast milk or nutrient-enriched preterm formula. Randomization was stratified according to whether the mother provided breast milk for her own infant. Thus, donor milk and preterm formula could be compared as sole diets in infants whose mothers did not provide their own milk or as a supplement to breast milk. Study B compared standard term formula or the preterm formula as sole diets or as supplements to the mother's milk. All infants with NEC had received enteral feeds. NEC developed in 51 of the 926 preterm infants (5.5%). Of those confirmed cases, 35% needed surgery and 26% died. Of the 86 infants exclusively fed donor breast milk, there were three cases (4%) of NEC, and among the 76 infants fed exclusively preterm formula, there were six cases (8%) of NEC. NEC was

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[16] Jocelyn Shulhan, *et al.*, *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*, 8 Adv Nutr. 80–91 (2017).

[17] *Id.*

[18] *See* Chowning R., *et al*., *A Retrospective Analysis of the Effect of Human Milk on Prevention of Necrotizing Enterocolitis and Postnatal Growth* 36 J Perinatol 221-4 (2016); Johnson TJ, et al., *Cost Savings of Human Milk as a Strategy to Reduce the Incidence of Necrotizing Enterocolitis in Very Low Birth Weight Infants*, 107 Neonatology 271–6 (2015); Sullivan, S., *et al.*, *An Exclusively Human Milk-Based Diet is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products*, 156 J Pediatr 562–7 (2010); Cristofalo EA, *et al.*, *Randomized Trial of Exclusive Human Milk versus Preterm Formula Diets in Extremely Premature Infants,* 163 J Pediatr1592-5 (2013).

[19] Lucas A., Cole TJ, *Breast Milk and Neonatal Necrotizing Enterocolitis*, 336 Lancet 1519-1523 (1990).

determined to be *six to ten times* more common in those fed bovine-based formula, and *three times* more common than in those who received the formula plus breast milk

32. The effects of human milk versus formula feeding were evaluated in another study, published in 1999.[20] That study specifically compared outcomes of 62 infants fed fortified human milk, which was defined as the mother's own milk plus Enfamil Human Milk Fortifier. 46 infants were fed exclusively the preterm formula Enfamil Premature Formula 24. The study found that infants fed with any amount of human milk were discharged earlier than infants fed preterm formula, despite significantly slower rates of weight gain and size. In addition, there was lower incidence of NEC and late onset of sepsis in infants fed fortified human milk as compared to those fed preterm formula. The study concluded that the unique properties of human milk promote an improved host defense and gastrointestinal function compared with the feeding of formula.

33. Another study was published in 2010, evaluating the benefits of an exclusively human milk-based diet compared with a diet of both human milk and bovine milk-based products in extremely premature infants.[21] Infants fed their own mothers' milk were separated into three different study groups: (1) HM100: pasteurized donor human milk-based human milk fortifier with an enteral intake of 100 mL/kg/d; (2) HM40: pasteurized donor human milk-based human milk fortifier with an enteral intake of 40 mL/kg/d; and (3) BOV: bovine milk-based human milk fortifier with an enteral intake of 100 mL/kg/d. The groups receiving an exclusively human milk diet had significantly lower rates of NEC and NEC requiring surgical intervention, as depicted in Figure 2, below.

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[20] Schanler RJ, *et al.*, *Feeding Strategies for Premature Infants: Beneficial Outcomes of Feeding Fortified Human Milk vs Preterm Formula*, 103 Pediatrics 1150-57 (1999).

[21] Sullivan, *supra* note 18.

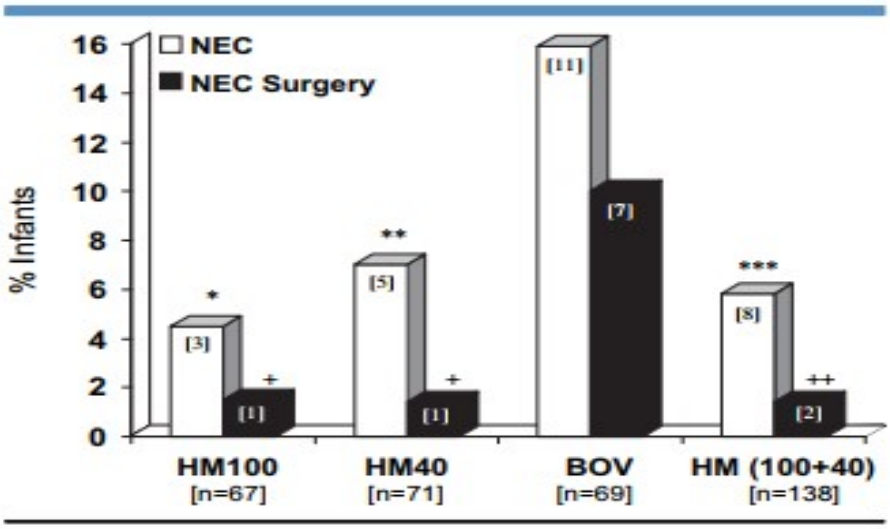

Figure 2. NEC and NEC surgery in study infants. There were significant differences in NEC among the 3 groups ($P = .05$), $^{*}P = .04$ vs BOV, $^{**}P = .09$ vs BOV, $^{***}P = .02$ vs BOV. There were significant differences in NEC requiring surgical intervention among the 3 groups ($P = .02$), $^{\dagger}P = .03$ vs BOV, $^{\dagger\dagger}P = .007$ vs BOV. [ ] refers to number of infants.

[22]

34. In another 2020 publication, the twelve-center randomized trial published in 2010,[23] that compared bovine milk derived fortifier to human milk derived fortifier, was reviewed and analyzed.[24] The new study noted that it was common practice to feed preterm infants a base diet comprising of only human milk, usually fortified with a bovine derived fortifier.[25] The study took the old data[26] and focused on the infants who had a diet comprised 100% of their mothers' own milk (*i.e.*, they had no donor milk or preterm formula). This allowed for an isolated comparison of the bovine derived fortifier and the human derived fortifier. The study found that the bovine derived fortifier was associated with a higher risk of NEC, NEC requiring surgery,

[22] *Id.*

[23] Sullivan, *supra* note 18.

[24] Lucas, *et al.*, *Preterm Infants Fed Cow's Milk-Derived Fortifier had Adverse Outcomes Despite a Base Diet of Only Mother's Own Milk*, 15 Breastfeeding Medicine 297-303 (2020).

[25] *Id.*

[26] Lucas, *supra* note 24.

reduced head circumference gain, and death.[27] Despite the high intake of the mother's own milk, the bovine derived fortifier was still associated with a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of NEC surgery or death. Thus, those fed a human derived fortifier were significantly advantaged in terms of a reduced incidence of morbidity. The authors concluded that the available evidence points to an increase in adverse outcomes with bovine derived fortifier, including NEC (Modified Bell's Staging Criteria Stage 2 or greater), NEC surgery or death, and surgical NEC.[28]

Parameter	*HMDF (n=82)*	*CMDF (n=32)*
NEC (Bell Stage 2 or greater)	3/82 (3.7%)	5/32 (15.6%)
NEC surgery or death[b]	3/82 (3.7%)	6/32 (18.8%)
Surgical NEC[b]	1/82 (1.2%)	3/32 (9.4%)
Death[b]	3/82 (3.7%)	4/32 (12.5%)
BPD	24/82 (29.3%)	11/32 (34.4%)
Ventilator days	Median 9.5 IQR=0.75, 41.25	Median 15.5 IQR=1, 50.25
ROP (grade 3 or 4)	6/82 (7.3%)	2/32 (6.3%)

[29]

[a]Chi-square/Fisher's exact test for categorical variables; for ventilator days, Wilcoxon's test.
[b]Note that for the index "NEC surgery or death" there are three versus six cases in the HMDF and CMDF groups; this is one less in each group than the sum of NEC surgery and death when shown individually. This is because in each diet group, one case had *both* NEC surgery and death (not counted twice in the index).
BPD, bronchopulmonary dysplasia; CMDF, cow's milk-derived fortifier; HMDF, human milk-derived fortifier; ROP, retinopathy of prematurity.

C. Defendant Knew of the Risks Associated with Bovine Formula

35. When sufficient maternal breast milk is not available, it has been widely recognized that alternative sources of enteral nutrition for preterm or low birth weight infants include donor breast milk or artificial formula.

36. There are several clinical trials comparing the effects of feeding preterm infants with human milk, human donor milk, and bovine milk-based products.

[27] Lucas, *supra* note 24.

[28] *Id.*

[29] *Id.*

37. A Cochrane Library meta-analysis, last updated in 2018, analyzed data from eight trials including 1,605 participants who were either preterm or low birth weight infants in a neonatal unit.[30] The combined data showed a higher risk of NEC in the formula-fed group. The studies compared the use of formula and donor breast milk. The meta-analysis showed that the overall risk of the infant developing NEC with donor breast milk was 3.7% and the overall risk with formula was 7% (4.5-10.7%). The analysis documented that there is a higher risk of NEC in the formula-fed group. Below is a summary of the studies that were examined as part of the meta-analysis:

a. **Term Formula versus Unfortified Donor Breast Milk:** the study evaluated the outcomes of preterm infants fed human milk compared to modified infant formula.[31] This study reported on 67 preterm infants from 1980 to 1982, comparing infants fed with unfortified donor milk and term formula. The results showed that three out of 26 infants on the formula milk developed NEC, whereas only one out of 41 infants receiving donor breast milk developed NEC—*a 300% difference*.

b. **Preterm Formula versus Fortified Donor Breast Milk:** the study evaluated growth, metabolic response, and development in very-low-birth-weight infants fed donor milk or enriched formula.[32] This study reported on 76 healthy infants of very low birth weights, comparing banked human milk and Similac Special Care protein-mineral–calorie-

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[30] Quigley, *et al.*, *Formula versus Donor Breast Mild for Feeding Preterm or Low Birth Weight Infants*, 6 Cochrane Database of Systematic Reviews (2018), https://pubmed.ncbi.nlm.nih.gov/29926476/.

[31] Gross SJ, *Growth and Biochemical Response of Preterm Infants Fed Human Milk or Modified Infant Formula*, 308 New England Journal of Medicine 237-41 (1983); Duke University Department of Pediatrics; Funded by Mead Johnson Nutrition.

[32] Tyson JE, *et al.*, *Growth, Metabolic Response, and Development in Very-Low-Birth-Weight Infants Fed Banked Human Milk or Enriched Formula. I. Neonatal Findings*, 103 Journal of Pediatrics 95-104 (1983).

enriched formula. Two of the infants on the formula developed NEC while none of the infants on the donor milk developed NEC.

c. **Preterm Formula versus Fortified Donor Breast Milk**: this study evaluated the clinical impact of infants fed bovine fortified breast milk.[33] Published in 1996, this trial involved 276 preterm infants who were fed a base diet of a mother's own milk, and if insufficient breast milk was available, bovine based preterm formula was added. The number of infants with NEC was 5.8% in the fortified group compared to 2.2% in the control group. The trial showed that the addition of bovine derived fortifiers to breast milk, as the sole intervention, more than doubled the combined incidence of confirmed NEC or sepsis.

d. **Preterm Formula versus Fortified Donor Breast Milk**: a randomized trial of extremely premature infants on donor human milk versus preterm formula was conducted.[34] This study, published in 2005, compared the differences in 243 infants fed with their mothers' milk, pasteurized donor milk plus Enfamil Human Milk Fortifier or Similac Human Milk Fortifier, and preterm formula (Enfamil Premature Formula). The results of this trial showed that infants who received their own mothers' milk had a 50% less chance of NEC and/or late-onset sepsis compared with infants fed either donor human milk or preterm formula.

e. **Preterm Formula versus Fortified Donor Breast Milk**: a randomized trial examining the use of exclusive human milk versus preterm formula diets in extremely

[33] Lucas A., *et al.*, *Randomized Outcome Trial of Human Milk Fortification and Developmental Outcome in Preterm Infants*, 64 Am J Clin Nutr 142-51 (1996); Supported by Mead Johnson (Evansville, IN) which also supplied the fortifier.

[34] Schanler RJ, *et al.*, *Randomized Trial of Donor Human Milk versus Preterm Formula as Substitutes For Mothers' Own Milk in the Feeding of Extremely Premature Infants*, 116 Pediatrics 400-6 (2005).

premature infants was conducted.[35] This study, published in 2013, examined 53 extremely premature infants fed exclusive diets of either bovine milk–based preterm formula, or donor human milk with human milk-based fortifier. The incidence of NEC in the bovine formula group was 21% (five cases) versus 3% in the human milk group (one case). Surgical NEC was significantly higher in the bovine formula group (four cases) than human milk group (no cases). It was concluded that in extremely preterm infants, given exclusive diets of preterm formula versus human milk, there was a significantly higher rate of surgical NEC in infants receiving preterm formula. The researchers concluded that this trial supported the use of an exclusive human milk diet to nourish extremely preterm infants in the NICU.

f. **Preterm Formula versus Fortified Donor Breast Milk**: this study examined the effect of supplemental donor human milk compared with preterm formula on neurodevelopment of very low birth-weight infants at eighteen months.[36] This trial evaluated 363 very low birth weight infants whose mother's breast milk became insufficient in four neonatal units in Ontario, California. The infant mother's milk was supplemented with either preterm formula (Similac Special Care or Enfamil Premature), or pasteurized donor breast milk supplemented with a fortifier (Similac Human Milk Fortifier or Enfamil Human Milk Fortifier), and a protein module (Beneprotein-Nestlé).

[35] Cristofalo EA, *et al.*, *Randomized Trial of Exclusive Human Milk versus Preterm Formula Diets in Extremely Premature Infants*, 163 Journal of Pediatrics 1592-95 (2013).

[36] O'Connor DL, *et al.*, *Effect of Supplemental Donor Human Milk Compared with Preterm Formula on Neurodevelopment of Very Low Birth-weight Infants at 18 months: A Randomized Clinical Trial,* 316 JAMA 1897-1905 (2016). This study was funded by the Canadian Institutes of Health Research and the Ontario Ministry of Health and Long-Term Care.

The study showed that the nutrient enriched donor milk was associated with a lower risk of NEC (1.7%) compared with feeding preterm formula (6.6%).

38. As demonstrated by these studies, although Defendant misleadingly markets and promotes Enfamil to make parents and healthcare providers believe that it is safe and necessary for growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil substantially increase the chance of a premature infant developing NEC, resulting in severe injury and death.

39. Despite the aforementioned science confirming the dangers of Defendant's bovine product in causing NEC and death in premature infants, Defendant took no action to change its product, packaging, guidelines, instructions, and warnings.

40. Defendant continues to sell its bovine formulas and/or fortifiers commercially at retail locations and online.

41. Despite knowing NEC's risks arising from the use of its bovine-based products, including its Enfamil product, Defendant failed to properly warn the consuming public, including parents of premature infants and medical and healthcare providers, that its bovine formulas and/or fortifiers, including Enfamil, significantly increase the risk that premature infants will develop NEC and/or death.

42. Despite knowing NEC's risks arising from the use of its bovine-based products, including its Enfamil product, Defendant failed to design its bovine-based products to make them safe and deceived the consuming public, including parents and healthcare providers of premature infants, into believing that the products were safe and necessary alternatives, supplements, and/or substitutes to human milk.

43. As a direct result of Defendant's failure to take action to make its bovine-based products safe and warn the consuming public of NEC's risks arising from the use of those products, Defendant's bovine formulas and/or fortifiers caused Kris Bloom to develop NEC, which resulted in her significant injuries. Prior to the administering of the formula to Kris Bloom, Defendant knew or should have known that its bovine formula and/or fortifier was not safe for use by premature infants, including Kris Bloom, yet it took no action to prevent the use of its product by premature infants.

44. Defendant knew or should have known that its bovine formula and/or fortifier would be used to feed premature infants, such as Kris Bloom, and knew or should have known that such use would significantly increase the risk of NEC in premature infants, including Kris Bloom, yet it took no action to prevent such use.

45. Defendant's formula is not safe to be used by premature infants, such as Kris Bloom, and Defendant knew or should have known it was unsafe, yet it failed to properly instruct or warn the FDA, NICUs, hospitals, doctors, and parents that its product was unsafe.

46. Despite Defendant's knowledge that its product was not safe for use by premature infants, including Kris Bloom, it also failed to provide detailed instructions or guidelines on when and how its product would be safe to use in premature infants, like Kris Bloom.

47. Notwithstanding substantial medical evidence establishing the extreme dangers that bovine formulas pose for premature infants, Defendant markets its bovine formulas and/or fortifiers as equally safe alternatives to breast milk and promotes its products as necessary for additional nutrition and growth. Defendant has specifically marketed its bovine formulas and/or fortifiers as necessary to the growth and development of premature infants, despite knowing its product poses a well-established and substantial risk to premature infants.

48. Despite the existence of safe, alternative human milk-based formulas and fortifiers, Defendant continues to misleadingly market and sell its bovine formulas and/or fortifiers under the guise of being safe for newborns, including premature infants, and despite knowing the significant health risk posed to infants by ingesting these products, especially to preterm, low weight infants, like Kris Bloom.

49. Defendant knows that its bovine formulas and/or fortifiers are causing NEC, devastating injuries, and death in premature infants, yet Defendant has taken no action to change its product, packaging, guidelines, instructions, and warnings to make them safe.

50. Defendant never informed Plaintiffs that its formula and/or fortifier could cause their baby to develop NEC and other severe resulting injuries.

51. Defendant never informed Plaintiffs that its formula and/or fortifier could cause their baby any harm, including the development of NEC and other severe resulting injuries.

52. Defendant never informed Plaintiffs that its formula and/or fortifier was made with bovine based ingredients.

53. Despite Defendant's knowledge of the numerous studies establishing that its products increase the risk of NEC in premature infants, Defendants never informed Plaintiffs of the studies establishing that bovine formula and/or fortifier were extremely dangerous to their baby.

54. Had Plaintiffs been informed of the facts, data, and science that linked the Defendant's product to its potential for causing NEC in their baby, they would not have allowed their baby to be fed Enfamil.

55. Due to Defendant's conduct, in not publicizing and/or distributing and/or warning of the dangers of using its bovine formulas and/or fortifiers in preterm, low weight infants,

Plaintiffs, nor any reasonably person, would have been able to have discovered the dangerous nature of Defendant's product or how it injured their child until shortly before the filing of this lawsuit.

CLAIMS ALLEGED

FIRST CAUSE OF ACTION
FAILURE TO WARN

56. Plaintiffs repeat and reallege the allegations in Paragraphs 1-55, above, as if fully set forth herein.

57. Defendant, as the manufacturer and/or seller of the infant formulas and/or fortifiers at issue in this litigation, owed a duty to the consuming public and Plaintiffs, to properly warn and provide adequate warnings, instructions, labeling, and/or packaging about the dangers and risks associated with the use of their products by preterm infants, specifically including, but not limited to, the risk of NEC.

58. Given the bovine formula and/or fortifier at issue is non-prescription, does not require a physician's recommendation, and is sold with packaging and labels meant to inform the average consumer. Thus, the learned intermediary doctrine does not apply.

59. The FDA has issued guidance specifically for the labeling of infant formulas, stating in part:

> Infant formulas are intended for a vulnerable population and may serve as a sole or primary source of nutrition for some infants during a critical period of growth and development. Caregivers of babies fed infant formula products must be able to trust that the information on the label is truthful, not misleading, and scientifically supported.[37]

[37] U.S. Food and Drug Administration, *FDA Issues Guidance for the Labeling of Infant Formula*, September 16, 2016, https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-guidance-labeling-infant-formula.

60. Defendant, as the manufacturer and/or seller of the subject products, had a non-delegable duty to design reasonably safe products; and thus, it cannot rely upon any intermediary, including physicians, other healthcare providers, or healthcare staff, to fully warn the end user of the hidden dangers and risks in its infant formula products that contain bovine-based ingredients, specifically as it relates to the serious injuries that may result in preterm infants due to the increased risk of NEC.

61. Defendant had a duty to manufacture and distribute infant formula products that were reasonably safe for their foreseeable uses. It was Defendant's duty to adequately warn of the unreasonable risk of harm posed by bovine-based ingredients in its formulas and/or fortifiers, specifically the increased risk of NEC, bodily injury, and even death, that may result with the use of its formulas by pre-term infants, like Kris Bloom.

62. Defendant knew or should have known, as a leader in the industry, that the formulas and/or fortifiers manufactured and/or distributed by Defendant were unreasonably dangerous because of Defendant's failure to warn of the adverse side effects, including NEC and/or death in preterm infants.

63. Specifically, Defendant breached its duty to the consuming public, including Plaintiffs, to warn of the foreseeable risks of the formulas and/or fortifiers at issue by:

a. failing to properly warn consumers, including, but not limited to, physicians, hospitals, hospital staff, healthcare providers, and parents and/or guardians, that their bovine formulas and/or fortifier products significantly increase the risk of NEC and death in preterm infants;

b. failing to provide consumers with adequate instructions on proper use and administration of the subject products when used on preterm infants;

c. failing to warn consumers that the subject products were unsafe and/or not intended for the consumption by premature infants, including Kris Bloom;

d. failing to warn consumers that its product caused an increased risk of NEC, specifically as it relates to preterm infants being enterally fed the subject products;

e. failing to provide consumers with proper instructions, labeling, and/or packaging on how to administer and/or feed the subject products to premature infants in order to decrease the risk of NEC and/or avoid other significant complications including death;

f. failing to insert warnings and/or instructions in its packaging of other alternatives to bovine formulas including human milk which poses a decreased risk of NEC;

g. providing instructions, packaging, and labeling containing warnings that were dangerously inadequate, vague, and did not warn that bovine based ingredients significantly increase the risk of NEC;

h. failing to provide a label and/or instructions that reflect prominent studies regarding the risks and benefits of bovine formulas and/or fortifiers;

i. failing to warn physicians and healthcare providers in the instructions, labeling, and/or packaging of the extreme risk associated with feeding premature infants bovine formula and/or fortifiers;

j. failing to provide detailed instructions to physicians and/or hospitals, and other healthcare providers on when to stop feeding the subject product to preterm infants;

k. failing to take adequate measures to warn parents and/or guardians of the dangers in using the subject products;

l. failing to warn and/or concealed that there is a significant risk of NEC in premature infants fed bovine based formula, despite knowing that numerous studies and scientific data have established that there is a significant risk of NEC in premature infants fed bovine based formula;

m. failing to place a prominent warning and instructions that would have prevented the feeding of the subject products to preterm infants, including Kris Bloom;

n. failing to establish an appropriate standard for safe use;

o. failing to provide statistical evidence of adverse effects regarding the feeding of its products to preterm infants;

p. failing to guide, instruct, and/or advise on when preterm infants should be administered the formula, the amount of formula and/or fortifier that should be administered, when the amount of formula and/or fortifier should be increased, the frequency of the administration of the formula and/or fortifier, when feeding with their formula and/or fortifier is not safe and/or inappropriate, and when preterm infants should stop using this formula and/or fortifier; and

q. failing to develop a protocol for hospitals and physicians with the elements to assure safe use.

64. Had physicians, hospitals, and other healthcare providers known of the extreme risk associated with feeding premature infants Defendant's bovine formula and/or fortifier, they would not have administered Defendant's unsafe product to Kris Bloom.

65. Had Plaintiffs known of the extreme risks associated with feeding premature infants bovine formula and/or fortifier, they would not have allowed Defendant's unsafe product to be administered to Kris Bloom.

66. As a direct and proximate result of Defendant's conduct, as described herein, Kris Bloom was administered and/or enterally fed the subject product causing her to develop NEC, and ultimately caused serious injuries.

67. As a direct and proximate result of Defendant's conduct, as described herein, Plaintiffs suffered significant damages and their lives have been significantly affected by the injuries of their baby.

SECOND CAUSE OF ACTION
STRICT LIABILITY FOR DEFECTIVE PRODUCT

68. Plaintiffs repeat and reallege the allegations in Paragraphs 1-55, above, as if fully set forth herein.

69. Defendant, as the manufacturer and/or seller of the infant formula and/or fortifier at issue, owed a duty to the consuming public, including Plaintiffs, to manufacture, sell, and distribute the formula and/or fortifier in a manner that was not unreasonably dangerous for its intended use.

70. Defendant knew or should have known that its formula and/or fortifier was intended for use on premature infants, like Kris Bloom, and that such use was unreasonably dangerous due to bovine formula and/or fortifier significantly increasing the risk of NEC and/or death.

71. Reliable scientific studies and data establish that bovine formulas and/or fortifiers, including those manufactured and distributed by Defendant, carry unreasonable risks of NEC and death, yet Defendant continued to market and sell its defective products for premature infants, like Kris Bloom.

72. Despite Defendant's knowledge of these significant risks, Defendant continued to market, sell, and distribute their defective products to premature infants.

73. Defendant's formula and/or fortifier, which was administered and/or enterally fed to Kris Bloom, was unreasonably dangerous.

74. Defendant failed to develop a human-based milk product which was safer for premature infants, despite knowing of the dangers of bovine formulas.

75. Defendant also failed to reformulate and/or redesign its formulas and/or fortifiers to make them safe, including by reducing the risks of NEC, even though it knew of safer, more effective alternatives.

76. As a direct result Defendant's conduct, as described herein, Defendant's unreasonably dangerous products were administered to Kris Bloom, causing her to develop NEC and sustain serious injuries.

77. As a direct and proximate result of Defendant's conduct, including developing, manufacturing, selling, and distributing its unreasonably dangerous bovine formulas and/or fortifiers, Plaintiffs suffered damages as their lives have been significantly affected by the injuries of their baby.

THIRD CAUSE OF ACTION
NEGLIGENCE

78. Plaintiffs repeat and reallege the allegations in Paragraphs 1-55, above, as if fully set forth herein.

79. Defendant, as the manufacturer, designer, seller, and distributor of the bovine formulas and/or fortifiers at issue, had a duty to the consuming public, including Plaintiffs, to exercise reasonable care to design, test, manufacture, inspect, and distribute a safe product that did

not present an unreasonable risk of harm to consumers when used in its intended manner and for its intended purpose.

80. At all relevant times, Kris Bloom was administered the formula and/or fortifier at issue in its intended manner and for its intended purpose.

81. Defendant negligently and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the bovine products at issue and thereby breached its duty to the consuming public, including Plaintiffs.

82. Specifically, Defendant breached its duty to the consuming public, including Plaintiffs, by:

a. failing to properly warn consumers, including but not limited to physicians, hospitals, hospital staff, healthcare providers, and parents and/or guardians, that its bovine products significantly increase the risk of NEC and death in preterm infants;

b. failing to provide consumers with adequate instructions on proper use and administration of the subject products when used on preterm infants;

c. failing to warn consumers that the subject products were unsafe and/or not intended for the consumption of premature infants including Kris Bloom;

d. failing to warn consumers that its product caused an increased risk of NEC, specifically as it relates to preterm infants being enterally fed the subject products;

e. failing to provide consumers with proper instructions, labeling, and/or packaging on how to administer and/or feed the subject products to premature

infants in order to decrease the risk of NEC and/or avoid other significant complications, including death;

f. failing to insert warnings and/or instructions in its packaging, notifying the consuming public of safe alternatives to bovine formulas and/or fortifiers, including human milk which decreases the risk of NEC;

g. providing instructions, packaging, and labeling containing warnings that were dangerously inadequate, vague, and did not warn that bovine based ingredients significantly increase the risk of NEC;

h. failing to establish a label and/or instructions that notify the consuming public of reliable scientific studies and data establishing the risks of bovine formulas and/or formulas;

i. failing to warn physicians and healthcare providers in the instructions, labeling, and/or packaging of the significant risk associated with administering premature infants bovine formulas and/or fortifiers;

j. failing to provide detailed instructions to physicians, hospitals, and healthcare providers regarding when to stop administering the subject product to preterm infants;

k. failing to take adequate measures to warn parents and/or guardians of the dangers in using the subject products;

l. failing to warn and/or concealed that there is a significant risk of NEC in premature infants fed bovine based formula, despite knowing that numerous studies and scientific data have established that there is a significant risk of NEC in premature infants fed bovine based formula;

m. failing to place a prominent warning and instructions that would have prevented the administering of the subject products to Kris Bloom;

n. failing to establish an appropriate standard for safe use;

o. failing to provide statistical evidence of adverse effects regarding the administration of its products to preterm infants;

p. failing to guide, instruct, and/or advise the consuming public regarding when preterm infants should be administered the subject product, the amount of formula and/or fortifier that should be administered, when the amount of formula and/or fortifier should be increased, the frequency of the administration of the formula and/or fortifier, when feeding with their formula and/or fortifier is not safe and/or inappropriate, and when preterm infants should stop using its formula and/or fortifier; and

q. failing to develop a protocol for hospitals, physicians, and healthcare providers to ensure safe use of its products.

83. As a direct result of Defendant's conduct, as described herein, Kris Bloom was exposed to Defendant's unreasonably dangerous infant formula and suffered from NEC and suffered severe injury.

84. As a direct result of Defendant's conduct, as described herein, Defendant's unreasonably dangerous formulas and/or fortifiers were administered to Kris Bloom causing her to develop NEC and suffer severe injury.

85. As a direct and proximate result of Defendant's negligent conduct, Plaintiffs suffered damages as their lives have been significantly affected by the injuries to their baby, to Kris Bloom.

FOURTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

86. Plaintiffs repeat and reallege the allegations in Paragraphs 1-55, above, as if fully set forth herein.

87. Defendant, as the manufacturer, designer, producer, seller, and distributor of the subject products, had a duty to the consuming public, including Plaintiffs, to provide truthful and accurate information about the risks of its bovine-based ingredients when the products are used in their intended manner and for their intended purpose.

88. At all relevant times, Kris Bloom was administered the products at issue in their intended manner and for their intended purpose.

89. Defendant breached its duty to the consuming public, including Plaintiff, by:

a. misrepresenting that its bovine formulas and/or fortifiers were safe for premature infants when it knew or should have known that its bovine formulas and/or fortifiers were unreasonably dangerous and caused NEC and death in premature infants;

b. misrepresenting that its bovine formulas and/or fortifiers have no serious side effects, when it knew or should have known the opposite to be true;

c. misrepresenting to consumers, including but not limited to, Plaintiffs here, as well as other parents and/or guardians, physicians and healthcare providers, that its bovine formulas and/or fortifiers were necessary to the growth and nutrition of premature infants, when it knew or should have known that its products were not necessary to achieve adequate growth and other safer alternatives are available;

d. misrepresenting that its bovine formulas and/or fortifiers are safe for premature infants;

e. misrepresenting that bovine formulas and/or fortifiers are necessary for optimum growth;

f. misrepresenting that bovine formulas and/or fortifiers are similar or equivalent and/or a safe alternative to human milk;

g. misrepresenting that the efficacy of bovine formulas and/or fortifiers were based on well-established studies and/or science; and

h. omitting and/or concealing that the subject products significantly increase the risk of NEC in premature infants, which can cause severe injury and death.

90. As a direct result of Defendant's conduct, as described herein, Kris Bloom was exposed to dangerous bovine formulas and/or fortifiers, causing her to contract NEC and suffer severe injury.

91. As a direct result of Defendant's conduct, as described herein, its unreasonably dangerous products were enterally administered to Kris Bloom causing her to develop NEC and suffer severe injury.

92. As a direct and proximate result of Defendant's conduct, as described herein, Plaintiffs suffered significant damages as their lives have been significantly affected by the injuries to their baby.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

93. Plaintiffs repeat and reallege the allegations in Paragraphs 1-55, above, as if fully set forth herein.

94. At all relevant times, Kris Bloom's parents and/or guardians, physicians, and/or other healthcare providers enterally administered the bovine formulas and/or fortifiers to Kris Bloom in their intended manner and for their intended purpose.

95. Defendant warranted, through marketing, advertisements, labels, packaging, and instructions that its products were safe and effective for their reasonably anticipated uses, including the enteral administration to premature infants.

96. Defendant implicitly warrants and markets as to its Enfamil line that Enfamil Neuro Pro, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, and Enfamil Premature Infant Formula 20 Cal with Iron are specifically intended to be administered to premature and/or low birthweight infants.[38]

97. Defendant also warrants that Enfamil has committed to premature babies and NICUs stating that "Enfamil has a long-standing commitment to helping every baby grow, develop and thrive."[39]

98. Defendant warrants that Enfamil NeuroPro Enfacare is: "proven to promote catch-up growth to help support developmental outcomes during the first year"; and the "#1 Pediatrician Recommended Brand."[40]

99. Defendant warrants and markets on its "For Healthcare Professionals" webpage, that: Enfamil Premature 20 Cal/fl oz, Enfamil Premature 24 cal/fl oz, Enfamil Premature 24 Cal/fl

[38] Enfamil, https://www.enfamil.com/products/preemie-formula/ (last visited Feb. 22, 2022).

[39] Enfamil, https://www.enfamil.com/why-enfamil/nicu-premature-baby/?gclid=EAIaIQobChMIjduloobx9QIV0AaICR239Ae2EAAYASAAEgLFHfD_BwE&gclsrc=aw.ds (last visited Feb. 22, 2022).

[40] Mead Johnson Nutrition, https://www.hcp.meadjohnson.com/s/product/a4R4J000000PpQjUAK/enfamil-neuropro-enfacare (last visited Feb. 8, 2022).

oz HP, and Enfamil Premature 30 Cal/fl oz, are each "a milk-based infant formula specifically formulated to meet the unique nutritional needs of rapidly growing premature or low birth weight infants who do not receive human milk."[41]

100. Defendant launched its "Early Kickoff" advertising campaign for Enfamil in early January 2022, releasing a Super Bowl advertisement featuring NFL player Mekhi Becton, who was born premature.[42] The Enfamil commercial itself, warranted that "in those critical first weeks, Enfamil is there for [premature babies] in NICUs with the nutrition babies need to get the best start in life."[43] The advertisement highlighted Enfamil's "longstanding commitment to and support of preemies living their fullest lives," with Enfamil branding and products visible throughout. Amardeep Khalon, GM of marketing nutrition at Enfamil, said of the campaign, in part:

> Our objective is to drive creative brilliance, bring to life, and amplify the brand purpose for Enfamil. We passionately believe that babies are the most important people in the world and that we play a critical role in helping them thrive through world class nutrition to help them fuel their wonder. We wanted to bring attention to the over 380,000 premature babies born in the US every year and the unique care and nutrition that they need. Even though nothing is better for babies than breastfeeding, unfortunately, not every baby can be breastfed. In those critical first few weeks, Enfamil is there for them in neonatal intensive care units with everything premature babies need to get the best start in life. Through the Early Kickoff campaign, we have creatively brought attention to the issues facing premature babies and how with the right care and nutrition they can thrive through the first ever premature Superbowl commercial. [44]

[41] Mead Johnson Nutrition, https://www.hcp.meadjohnson.com/s/products?category=Formula (last visited Feb. 8, 2022).

[42] Enfamil US, *Expected: February 13. Born: 6 Weeks Early*, YouTube (Jan. 27, 2022), https://www.youtube.com/watch?v=aVVZ1R6MS-k.

[43] *Id.*

[44] Robert Goldrich, *McCann, MRM Debut "Premature" Super Bowl Spot For Enfamil, NICU Babies*, (Jan. 21, 2022).

101. Thus, despite the existence of safe, alternative human milk-based formulas and fortifiers, Defendant continues to misleadingly market and/or sell its bovine formulas and/or fortifiers under the guise of being safe for newborns, despite knowing the significant health risk posed by ingesting these products, especially to preterm, low weight infants, like Kris Bloom.

102. Defendants warranted that their products were necessary for growth and safe for use.

103. Defendant Mead warrants that Enfamil Premature 30 Cal/fl oz is a:

> milk-based infant formula specifically formulated to meet the unique nutritional needs of rapidly growing premature or low-birth-weight infants who do not receive human milk. The Enfamil Premature Nutrition portfolio is the only premature infant formula line designed to meet the latest Global Expert Recommendations for all labeled nutrients. Protein is a major driver of lean mass growth and neuro-cognitive outcomes, and Enfamil Premature Nutrition supports these protein needs. Enfamil Premature 30 Cal/fl oz is a versatile formula. It is ready to use at its full concentration for a calorically dense 30 Cal/fl oz formula or can be customized for infants in the NICU. It can be mixed with Enfamil Premature 24 Cal to attain between 25 and 29 Cal/fl oz, or increase the protein content by mixing with Enfamil Premature 24 Cal HP.[45]

104. Defendant also warrants that "Enfamil Premature is the best formula for newborns with a low birth weight. It has high levels of the nutrients that help promote catch up growth and support a developing immune system.[46]

105. Nowhere on Defendant's promotional website[47], does Defendant mention *any* of NEC's risks. To the contrary across its promotional web page Defendant expressly and implicitly represents that its bovine products are safe for use with premature infants. That is false and

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[45] Mead Johnson Nutrition, https://www.hcp.meadjohnson.com/s/product/a4R4J000000PpQkUAK/enfamil-premature-30-calfl-oz (last visited Feb. 19, 2022).

[46] Enfamil, https://www.enfamil.com/articles/best-baby-formula-for-babys-needs/ (last visited Feb. 13, 2022).

[47] https://www.hcp.meadjohnson.com/s/product/a4R4J000000PpQkUAK/enfamil-premature-30-calfl-oz

misleading. Defendant's advertisements claim to give proper nourishments, but fails to disclose the risk of NEC.

106. Despite the existence of safe, alternative human milk-based formulas and fortifiers, Defendant continues to market and/or sell its bovine formulas and/or fortifiers under the guise of being safe for newborns, despite knowing the significant health risk posed by ingesting these products, especially to preterm, low weight infants, like Kris Bloom.

107. The bovine formulas and/or fortifiers did not conform to these implied representations because Defendant manufactured, sold, and advertised the formula, which was not similar or equivalent to human milk, was not necessary for growth, and which was not based upon current data and science establishing problematic health risks of bovine-based formula to pre-term infants that caused significant harm and/or death to premature infants.

108. As a direct result of Defendant's conduct, as described herein, unreasonably dangerous bovine formulas and/or fortifiers were administered to Kris Bloom, causing her to develop NEC and suffer serious injuries.

109. As a direct and proximate result of Defendants' conduct, as described herein, Plaintiffs have suffered damages as their lives have been significantly affected by the injuries to their baby, Kris Bloom.

SIXTH CAUSE OF ACTION
PRODUCTS LIABILITY – DESIGN DEFECT
UNDER ILLINOIS LAW

110. Plaintiffs repeat and reallege the allegations in Paragraphs 1-55, above, as if fully set forth herein.

111. Defendant's bovine formulas and/or fortifiers, which were consumed by Kris Bloom and which caused her injuries, were defective in their design or formulation in that they are not reasonably fit, suitable, or safe for their intended purpose and/or the foreseeable risks exceed

the benefits associated with their design and formulation. The products were unreasonably dangerous in design.

112. At all relevant times, Defendant's bovine formulas and/or fortifiers expected to reach, and did reach, consumers in the State of Illinois and across the United States, including Plaintiffs, without substantial change in the condition in which they were sold.

113. At all relevant times, Defendant's bovine formulas and/or fortifiers were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendant in a defective or unreasonably dangerous condition at the time placed in the stream of commerce in ways, which include, but are not limited to, one or more of the following:

a. when placed in the stream of commerce, the bovine formulas and/or fortifiers contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting Kris Bloom to risks that exceeded the benefits of the subject product, including personal injury and death;

b. when placed in the stream of commerce, Defendant's formulas and/or fortifiers were defective in design and formulation, making the use of Defendant's products more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with non-bovine formulas and/or fortifiers;

c. the design defects with Defendant's formulas and/or fortifiers existed before they left the control of Defendant;

d. the harmful side effects of Defendant's formulas and/or fortifiers outweighed any potential utility;

e. Defendant's formulas and/or fortifiers were not accompanied by adequate instructions and/or adequate warnings to fully apprise consumers, including Plaintiffs, of the full nature and extent of the risks and side effects associated with their use; and

f. at the time Defendant's formulas and/or fortifier's left Defendant's control, there existed one or more safe, alternative designs for said products, with such alternative design(s) capable of preventing Plaintiffs damages, and the danger of the damage from Defendant's bovine formulas and/or fortifiers outweighed the burden on Defendant of adopting the alternative design(s).

114. Defendant knew or should have known that its respective products would be administered to premature infants, including Kris Bloom, and that such use would significantly increase the risk of NEC and significant injury to her.

115. Defendant took no actions to prevent the administration of its bovine formulas and/or fortifiers to premature infants, including Kris Bloom.

116. The formulas and/or fortifiers were designed, manufactured, and distributed by Defendant.

117. Defendant's bovine formulas and/or fortifiers were not safe to be administered to premature infants, including Kris Bloom, and Defendant knew or should have known they were unsafe.

118. Despite Defendant's knowledge that its products were unreasonably dangerous when administered to premature infants, it failed to provide any instructions or guidelines on when and how its products would be safe to administer to or with a premature infant, like Kris Bloom.

Defendant misleadingly marketed its respective products as safe and beneficial for premature infants, like Kris Bloom.

119. As a direct and proximate result of the foregoing acts and omissions, Defendant's formulas and/or fortifiers were a substantial factor in causing Kris Bloom's NEC and her serious injuries arising therefrom.

120. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs suffered damages as their life has been significantly affected by the injuries to their baby, Kris Bloom.

SEVENTH CAUSE OF ACTION
VIOLATION OF THE ILLINOIS CONSUMER FRAUD
AND DECEPTIVE TRADE PRACTICES ACT 815 ILCS 505/1, *et seq.*

121. Plaintiffs repeat and reallege the allegations in Paragraphs 1-55above, as if fully set forth herein.

122. The Illinois Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505/2, states that, "[u]nfair methods of competition and unfair or deceptive acts or practices . . . are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby."

123. By the conduct described in detail above and incorporated herein, Defendant engaged in unfair or deceptive acts in violation of the Illinois Consumer Fraud and Deceptive Business Practices Act.

124. Defendant's unfair and deceptive practices include:

a. developing a systematic, pervasive, effective, and manipulative marketing scheme designed to make parents and healthcare providers believe Enfamil and

other bovine products were as safe, or even safer, than human milk; including that it was safe for premature infants;

b. engaging in advertising, promotion and marketing inducing parents and healthcare providers of premature infants to not breastfeed by diminishing the public perception of the importance of breastfeeding, and placing formula feeding on an equivalent level;

c. concealing and omitting the risks of NEC associated with the use of Enfamil and bovine milk by premature infants;

d. knowingly and falsely representing that Defendant's formulas and/or fortifiers were fit to be used for the purpose for which it was intended; and

e. representing that its products have characteristics, ingredients, uses, benefits, or quantities that they do not have.

125. Defendant's false and misleading representations and omissions concerning Enfamil and bovine milk are material facts that a reasonable person would have considered when deciding whether or not to purchase or use Enfamil.

126. Defendant's misleading omissions and representations concerning the risks of Enfamil, and Defendant's scheme to promote Enfamil and other bovine milk products as no less safe than human milk: (a) were against public policy; (b) were immoral, unethical, oppressive, and unscrupulous; and (c) caused substantial injuries to consumers.

127. Defendant intended for parents and healthcare providers, including the parents and healthcare providers of Kris Bloom, to rely on its misleading representations and omissions regarding Enfamil and other bovine milk products.

128. Defendant's unfair scheme to promote Enfamil and bovine milk products, and its deceptive representations and omissions concerning Enfamil and other bovine milk products, occurred in the course of conduct involving trade or commerce.

129. Kris Bloom's healthcare providers relied upon Defendant's misrepresentations and omissions in determining which product to administer to her, and Kris Bloom's parents were deceived into not objecting to Defendant's products by virtue of Defendant's misrepresentations and omissions and deceptive marketing campaigns.

130. As a direct and proximate result of Defendant's deceptive and unfair conduct, described above, Kris Bloom was administered Enfamil and sustained injuries and damages as described herein.

131. As a direct and proximate result of Defendant's deceptive and unfair conduct, described above, Astrid Moise suffered damages, as described herein, as her life has been significantly affected by the injuries to her baby, Kris Bloom.

EIGHTH CAUSE OF ACTION
VIOLATION OF THE FLORIDA
DECEPTIVE AND UNFAIR TRADE PRACTICES ACT
Fla. Stat. § 501.201, *et seq*.

132. Plaintiffs repeat and reallege the allegations in Paragraphs 1-55 above, as if fully set forth herein.

133. The Florida Deceptive and Unfair Trade Practices Act ("FDUTPA") makes unlawful "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." Fla. Stat. § 501.204(1).

134. By the conduct described in detail above and incorporated herein, Defendant engaged in unfair or deceptive acts in violation of Fla. Stat. § 501.204(1).

135. Defendant's unfair and deceptive practices include:

a. developing a systematic, pervasive, effective, and manipulative marketing scheme designed to make parents and healthcare providers believe Enfamil and other bovine products were as safe, or even safer, than human milk; including that it was safe for premature infants;

b. engaging in advertising, promotion and marketing inducing parents and healthcare providers of premature infants to not breastfeed by diminishing the public perception of the importance of breastfeeding, and placing formula feeding on an equivalent level;

c. concealing and omitting the risks of NEC associated with the use of Enfamil and bovine milk by premature infants;

d. knowingly and falsely representing that Defendant's formulas and/or fortifiers were fit to be used for the purpose for which it was intended; and

e. representing that its products have characteristics, ingredients, uses, benefits, or quantities that they do not have.

136. Defendant's false and misleading representations and omissions concerning Enfamil and bovine milk are material facts that a reasonable person would have considered when deciding whether or not to purchase or use Enfamil.

137. Defendant's misleading omissions and representations concerning the risks of Enfamil, and Defendant's scheme to promote Enfamil and other bovine milk products as no less safe than human milk: (a) were against public policy; (b) were immoral, unethical, oppressive, and unscrupulous; and (c) caused substantial injuries to consumers.

138. Defendant's misleading omissions and representations concerning the risks of Enfamil, and Defendant's scheme to promote Enfamil and other bovine milk products as no less safe than human milk had the capacity to deceive a substantial portion of the purchasing public.

139. Defendant intended for parents and healthcare providers, including the parents and healthcare providers of Kris Bloom, to rely on its misleading representations and omissions regarding Enfamil and other bovine milk products.

140. Defendant's unfair scheme to promote Enfamil and bovine milk products, and its deceptive representations and omissions concerning Enfamil and other bovine milk products, occurred in the course of conduct involving trade or commerce.

141. Defendant's unfair scheme to promote Enfamil and bovine milk products, and its deceptive representations and omissions concerning Enfamil and other bovine milk products, affected the public interest, including the health of Florida children.

142. Kris Bloom's healthcare providers relied upon Defendant's misrepresentations and omissions in determining which product to administer to her, and Kris Bloom's parents were deceived into not objecting to Defendant's products by virtue of Defendant's misrepresentations and omissions and deceptive marketing campaigns.

143. As a direct and proximate result of Defendant's deceptive and unfair conduct, described above, Kris Bloom was administered Enfamil and sustained injuries and damages as described herein.

144. As a direct and proximate result of Defendant's deceptive and unfair conduct, described above, Astrid Moise suffered damages, as described herein, as her life has been significantly affected by the injuries to her baby, Kris Bloom.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Defendant on each of the above-stated Claims as follows:

A. For general damages in a sum in excess of this Court's jurisdictional minimum;

B. For medical, incidental, and hospital expenses, according to proof;

C. For pre-judgment and post-judgment interest, as provided by law;

D. For consequential damages in excess of this Court's jurisdictional minimum;

E. For compensatory damages in excess of this Court's jurisdictional minimum;

F. For punitive damages;

G. For treble damages as defined by various statutes herein;

H. For attorneys' fees, expenses, and costs of this action; and

I. For all other and further relief that this Court deems appropriate.

JURY DEMAND

Plaintiffs hereby demand a trial by jury as to all claims so triable.

Dated: April 27, 2022

Respectfully submitted,

/s/ Adam J. Levitt

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* *pro hac vice* motions to be filed

CIVIL COVER SHEET

The ILND 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. ***(See instructions on next page of this form.)***

I. (a) PLAINTIFFS

KRIS BLOOM, by and through her natural mother and guardian, Astrid Moise, and Astrid Moise, individually

(b) County of Residence of First Listed Plaintiff
(Except in U.S. plaintiff cases)

(c) Attorneys *(firm name, address, and telephone number)*

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DEFENDANTS

MEAD JOHNSON & COMPANY, LLC A/K/A MEAD JOHNSON NUTRITION COMPANY

County of Residence of First Listed Defendant
(In U.S. plaintiff cases only)
Note: In land condemnation cases, use the location of the tract of land involved.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Check **one** box, only.)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government not a party.)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate citizenship of parties in Item III.)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(For Diversity Cases Only.)*

*(Check **one** box, only for plaintiff and **one** box for defendant.)*

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☒ 1	Incorporated *or* Principal Place of Business in This State	☐ 4	☒ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business in Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Check **one** box, only.)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loan (Excludes Veterans)
- ☐ 153 Recovery of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 530 General
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Habeas Corpus:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

PROPERTY RIGHTS
- ☐ 820 Copyright
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016 (DTSA)

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729 (a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act (TCPA)
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Arts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/Accommodations
- ☐ 445 Amer. w/ Disabilities-Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus – Alien Detainee (Prisoner Petition)
- ☐ 465 Other Immigration Actions

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAXES
- ☐ 870 Taxes (U.S. Plaintiff or Defendant
- ☐ 871 IRS—Third Party 26 USC 7609

V. ORIGIN *(Check **one** box, only.)*

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District (specify)
- ☐ 6 Multidistrict Litigation - Transfer
- ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

(Enter U.S. Civil Statute under which you are filing and write a brief statement of cause.)
28 U.S.C. Sec. 1332, Product Liability, Negligence, Violations of Consumer Protection Acts

VII. PREVIOUS BANKRUPTCY MATTERS

(For nature of suit 422 and 423, enter the case number and judge for any associated bankruptcy matter previously adjudicated by a judge of this Court. Use a separate attachment if necessary.)

VIII. REQUESTED IN COMPLAINT:

☐ Check if this is a **class action** under Rule 23, F.R.CV.P.

Demand $

CHECK Yes only if demanded in complaint:
Jury Demand: ☒ Yes ☐ No

IX. RELATED CASE(S) IF ANY *(See instructions):*

Judge Case Number

X. Is this a previously dismissed or remanded case? ☐ **Yes** ☒ **No** **If yes, Case #** **Name of Judge**

Date: 04/27/2022

Signature of Attorney of Record /s/ Adam J. Levitt

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority for Civil Cover Sheet

The ILND 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use
(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the
(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. Origin. Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.